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10/774,092	02/06/2004	Ernesto A. Brovelli	AM1150	7125

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,092	BROVELLI ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-25* is/are pending in the application.

4a) Of the above claim(s) *8-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-7 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3 and 5-25 are pending in the application.

Claims 8-22 were withdrawn from the merits as being directed toward a non-elected invention in the previous Office Action.

Claims 23-25 were newly added in the amendment filed 9/22/06.

Claims 1, 3, 5-7 and 23-25 were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5-7 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, Applicant is now claiming that the marker compounds and transcriptional products are tested from a preparation of Echinacea as well as claiming that transcriptional products are tested on extracts of Echinacea (claims 24-25) It cannot be found in the Instant specification as filed where transcriptional products such as Interleukins were quantified from Echinacea extracts. Rather, it is clear from the Instant specification that two different tests were preformed; Extraction of Echinacea with methanol/water in order to quantify chicoric acid content, and a separate, distinct test for immunopotentiating activity with Echinacea raw powder. Applicant is asked to either point out in the Instant specification where the new information is found, or to delete the New Matter in the claims, or to amend the claims accordingly in order to overcome this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5-7 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 24 both state the term 'acceptable'. The term "acceptable" in claims 1 and 24 is a relative term which renders the claim indefinite. The term

"acceptable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Because claims 3, 5-7, 23 and 25 depend either directly or indirectly upon claims 1 and 24 respectively and do not correct the indefinitess of either claims 1 or 24, these claims are also considered indefinite in that these claims necessarily possess all of the limitations of claims 1 or 24.

Claim Rejections - 35 USC § 103

Claims 1, 3 and 5-7 remain rejected and claim 24 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over A in view of C or B in view of C; wherein A = Seidler – Lozykowska et al. (2003), B= Dou et al. (2001 – Abstract) and C= Rininger et al. (2000). Seidler – Lozykowska et al. may be refered to as SL et al.

Applicant's arguments were fully considered, but not found persuasive.

Applicant argues that the "...Office action fails to set forth a *prima facie* case of obviousness" in that the Applicant alleges that the combination of Seidler-Lozykowsa et al. and Rininger et al. do not set forth a *prima facie* case. Applicant argues that "until applications' disclosure, no reference (or combination of references) taught a method

for standardizing an Echinacea biomarker level and identifying a material that augments an immune stimulatory response based on harvest window" (pp. 2-3 Arguments). It is noted that the claims do not state 'standardizing'. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., standardizing) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, many of the claims are quite broad and do not specifically recite any specific harvest time, or any specific product. Further, it is noted that the 'product' and the 'biomarker'; e.g., chicoric acid and IL-1 for example, are not clearly scientifically demonstrated as being proportional. Further, the claims do not state that the level of chicoric acid and the immunostimulatory products such as IL-1 are proportional. For example, the specification teaches that "..no definitive connection exists between any specific marker alone and observed immune-modulating activity....[0017]. Therefore, the selection of immune-modulating activity and that of a 'product' such as chicoric acid are measured simultaneously, but respectively. As stated keenly in the previous Office Action, one of ordinary skill in the art would have been motivated to test Echinacea products for chicoric acid content, as well as immunostimulatory activity, because each of these were already known in the art to be desirable characteristics of Echinacea.

Additionally, the claims are broad enough to read on taking *two* measurements of cell-induced immuno-response products (e.g., IL-1) and choosing the best of the two measurements because the claims simply state 'a plurality' which can be drawn toward more than one lacking any specific definition in the Specification. In this respect, the term 'optimal' in the claim is very broad, and the term 'acceptable' may mean *any* concentration (see 112 Second rejection *supra*). The specification also teaches that "As a plant-based medicinal product, standardization to a marker such as chicoric acid is important to meet market or regulatory expectations". This concept is well-known in the art as evidenced by the references as keenly pointed out in the previous Office Action as well as below.

Applicant argues

...neither Seidler-Lozykowska et al. nor Rininger et al. suggest or motivate one to combine these references. Seidler-Lozykowska et al. are concerned with defining the best harvest times base as related to maximizing concentration of polyphenolic acids...Seidler-Lozykowska et al. does not suggest or motivate one to look for other parameters that may intersect with, or complement, polyphenolic acid concentration and the efficacy of Echinacea. Rininger et al. are not concerned at all with harvest time, but seek to explain the variability of Echinacea

raw materials and commercially available products... (p. 4, Remarks, Teachings of the prior art').

First, it is again noted that all of the claims are not directed toward a specific product and biomarker. It is clear from Rininger that what was investigated was immunostimulatory activity of Echinacea; via quantitatively assessing transcriptional products (cytokines) produced by RAW 264.7 cells in response to contact with Echinacea. Therefore, what was known in the art at the time the Invention was made was that Echinacea had immunostimulatory properties which were scientifically investigated. What was further known in the art was that Echinacea could be tested *in-vitro* for immunopotentiating ability by measuring transcriptional products such as TGF and IL produced by RAW 264.7 cells. Therefore, it was well known at the time the Invention was made that amount of these transcriptional products produced by RAW 264.7 cells were proportional to the plant's immuno-potentiating activity (see Rininger et al., Figures 1 and 2 for example). Rininger et al. further specifically stated that that "Echinacea immunostimulatory activity varied significantly from lot-to-lot of raw material from the same supplier and may reflect growth conditions, time of harvest, milling and storage conditions" (p. 10). Again, analyzing Echinacea plants at different stages for particular immuno-potentiating compounds was known in the art according to Dou et al. as well as Seidler – Lozykowska et al. (2003). Therefore, the ordinary artisan would have been motivated to determine the optimal harvest window of Echinacea in order to obtain plant material which possessed maximum immunopotentiating effects.

Applicant argues "Similarly, Duo et al. do not discuss optimal harvest time. Even though the reference states that 'the content of chicoric acid and yield were the highest in the overground part of E.purpurea before and after the bloomy stage', the term 'optimal' is generally understood to mean 'most desirable or satisfactory' ...They do not suggest looking for references that discuss immunostimulatory activity to determine a more specific harvest time" (p. 10, Remarks). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is noted that the Dou et al. reference is not used alone, but is combined with Rininger et al. in order to produce this rejection. It is deemed that in the case of Duo et al., Duo et al. reported the 'optimal' time for harvest of the Echinacea which was before and after the bloomy stage. It is noted that the claims state 'a plurality' but do not state what 'plurality' means. It is deemed that a 'plurality' is more than one. Therefore, it is deemed that, in the broadest sense, the 'optimal' harvest time is chosen from at least two measurements. Here, it is clear that Duo et al. performed several measurements on chicoric acid concentration.

In the Instant case, Applicant is alleging that the novelty in the method claims lies in the process of harvesting the plant at a plurality of maturation stages to measure for levels of transcriptional products made from monocyte cell cultures and indicates that

"Rininger does not suggest or motivate one to search for a reference such as Dou et al.". However, the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); Ex parte Clapp, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection); and Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning). Further, as stated previously, Rininger suggest that the variability of transcriptional products of the RAW 264.7 cells could have been related to harvest time. It was clear from the art, according to Dou et al. and SL et al., that endogenous immunopotentiating products produced by Echinacea vary in amount during growth, and therefore indicate that it was desirable to harvest Echinacea at times where active immune enhancing compounds are at their peak volume. Therefore, one of ordinary skill in the art would be motivated to find the optimal harvest time of Echinacea by testing plural samples of Echinacea taken from different growth stages in order to test

these plant samples according to the methods set forth by Rininger et al. and find the 'optimum' time of harvest. The ordinary artisan would have had been motivated to find the optimal harvest time in order to harvest Echinacea with maximum immunopotentiating ability. Further, it is deemed that all of the references are analogous art; each reference navigated toward detecting and testing immunopoteniating products and/or abilities of the Echinacea plant and are thus considered pertinent to the claimed invention.

Applicant argues that "Rininger does not suggest or motivate one to search for a reference such as Dou et al." (p. 4, Remarks). However, as stated *supra*, one of ordinary skill in the art would be motivated to measure the degree of immunopotentiating activity in various growth stages of Echinacia by measuring TNF and IL in PB MC's especially since Rininger specifically suggested the link of varying levels of these growth factors/cytokines with factors such as harvest time.

Applicant argues that the combination of the references would not provide one of ordinary skill in the art with any reasonable expectation of success (p. 5, Remarks). Applicant states that "Rininger et al. specifically state that Echinacea extracts, etc. did not produce immunostimulatory activity....In fact, Rininger states that, "Echinacea extracts standardized to [biomarkers] phenolic acid or echinocaside content and fresh pressed juice preparations were found to be inactive as immunostimulatory agents, but did not display, to varying degrees, anti-inflammatory and antioxidant

properties'...Rininger teaches away from the ability to find immunostimulatory activity from Echinacea materials prepared by methods other than their stimulated digestion protocol to emulate oral dosing" (p. 5, Remarks). However, it is clearly apparent that Echinacea raw herb powders had significant immunopotentiating activity, which was already known in the art according to Rininger et al.; as Echinacea was known to stimulate cytokine production in macrophages/mononuclear cells (see p. 2, third full paragraph, Figures 1, 2 and 5 for example). With regard to Applicant's argument that Rininger et al. 'teach away' from finding immnostimulatory activity by any other method than their stimulated digestion protocol, first, it is noted that the claims state 'comprising' which is open language. The term 'comprising' allows the inclusion of method steps in addition to those which are specifically claimed. Further, it is true that Rininger et al. submit the Echinacea products to simulated digestion prior to treatment of RAW 264.7 cells. However, it is deemed that the simulated digestion protocol carried out by Rininger et al. is actually more advantageous because the end product of the simulated digestion would more closely relate to compounds which would actually be bioavailable. Second, the claims state "determining optimal harvest window of Echinacea plants...adding a preparation of the plant to a monocyte cell culture". Applicant argues that the term 'preparation' is defined as being an Echinacea plant powder or extract. Here, it is deemed that the digested Echinacea disclosed by Rininger et al. fits the description of an Echinacea 'preparation' because Rininger et al. also performed the tests with powdered Echinacea/root of Echinacea. Further, in light of Applicant's Specification, wherein the Echinacea powder is dissolved in DMSO prior to

administration to the cells, it is deemed that the term 'preparation' is broad enough to be directed toward digested plant product. Applicant additionally argues that there would not be reasonable expectation of success in combining SL et al. or Dou et al. because only Rininger et al. teach that only the digested Echinacea product, and not Echinacea product dissolved in DMSO provided for production of TNFα (p. 11, Remarks). However, again, Applicant is arguing limitations which are not present in the claims in that the claims do not specifically state how the Echinacea products are prepared. Although claims are read in light of the Specification, limitations from the Specification are not read into the claims.

Applicant argues that 'selecting a maturation stage with an acceptable concentration of marker compound and a most potent induction activity is absent from the combination" (p. 12, Remarks). Applicant argues that the rejection is faulty for two reasons. First, Applicant argues that Rininger et al. "state that their 'data highlight the variability of natural products and, for Echinacea could represent non-optimal harvest time, environmental conditions, or storage factors that govern production and preservation of Echinacea's immunostimulatory activity'...This statement teaches numerous possible choices and would require each to be tried until one possibly arrived at a successful result. Rininger gives no indication of which parameters were critical and no direction as to which of the possible choices is likely to be successful' (p. 12, Remarks). However, it was clear from Dou et al. and SL et al. that endogenous products of Echinacea varied throughout growth. Therefore, one of ordinary skill in the

art would have had a reasonable expectation that active ingredients; and also immunopotentiating ability of Echinacea would have also varied throughout growth since the immunopotentiating ability of Echinacea is due its endogenous products such as polysaccharides.

Applicant again argues that Rininger teaches away from the claimed invention in that Rininger teaches that 'through a simulated digestive protocol, the immunostimulatory activity was detected' and that, 'cells with Echinacea purpurea herb test material dissolved in traditional solvents for *in vitro* studies, such as demethyl sulfoxide, were inactive for production of TNF – α and NO as activation biomarkers' (p. 12, Remarks). However, as stated previously, Applicant is arguing limitations which were not claimed; that is, the Instant claims do not particularly specify that the Echinacea product is dissolved in DMSO. Further, as previously stated, it is deemed that Rininger et al. satisfy the requirements of the term 'preparation' in that they test digested powdered Echinacea in the macrophage cells.

Applicant concludes that that the Office action fails to set forth a *prima facie* case of obviousness because one of ordinary skill in the art would not be motivated to combined the references to arrive at the Instantly claimed invention (pp. 12-13, Remarks).

However, Rininger et al. state that it had already been determined in the art that substances such as polysaccharides isolated from Echinacea possessed immunopotentiating activity (again, page 2, second full paragraph). Although Rininger et al. did not specifically indicate that they measured chicoric acid, they did specifically teach that "The marker compounds *commonly standardized for in Echinacea extracts are phenolic (caffeic) acid derivatives. These compounds have antioxidant and anti-inflammatory properties*" (p. 9, first full paragraph – emphisis added). Chicoric acid is a caffeic acid derivative, as it is an ester of caffeic acid and is a well-known medicinally-active product as taught by SL et al. for example. Therefore, one of ordinary skill in the art would have been motivated to test different growth stages of Echinacea for optimal chicoric acid content because it was well known in the art that chicoric acid was an active anti-inflammatory agent. Furthermore, it was already well known in the art to standardize Echinacea products for amounts of caffeic acid derivatives as taught by Rininger et al. as well as SL et al. One of ordinary skill in the art would have had a reasonable expectation that measuring different growth stages of Echinacea for optimum activity; that is, for optimum immunopotentiating activity, and optimum amounts of known active agents would have been advantageous in producing Echinacea herbs with maximum benefit. Also, although Rininger et al. did not find much immunopotentiating activity in the tested extracts of Echinacea, it is deemed that they none-the-less examined these extracts for immunopotentiating activity. Further, claim 24 is directed toward any extract of Echinacea. One of ordinary skill in the art would

have been motivated to test extracts of Echinacea from different stages of growth in order to collect an extract of Echinacea with good immunopotentiating activity.

Applicant tested the Echinacea plant at various stages of growth. Although the prior art did not specifically test at different stages of growth, it is clear from Rininger et al. that the cytokine production was measured with regard to different lots of Echinacea and again, that Rininger et al. suggested that harvest time may be the cause of variations in immunopotentiating levels (see Rininger et al. p. 7, first full paragraph). Additionally, the various lots of Echinacea tested by Rininger et al., were probably harvested at different time since they were obtained from different sources. Again, because endogenous phytochemicals of Echinacea were known to fluctuate dependant upon plant growth (SL et al. and Dou et al.). Thus, it is determined that ***the prior art as a whole suggested the desirability of the claimed invention***; in that one of ordinary skill in the art would have been motivated to test Echinacea for maximum imunopotentiating activity at various stages during its growth in order to manufacture Echinacea products which advantageously possessed maximal immunopotentiating activity.

Claims 1, 3 and 5-7 remain rejected and claims 23-26 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over A in view of C in view of D or B in view of

C in view of D; wherein A = Seidler – Lozykowska et al. (2003), B= Dou et al. (2001 – Abstract), C= Rininger et al. (2000) and D=Wyllie et al. (US 2003/0235890). Seidler – Lozykowska et al. may be refered to as SL et al.

The teachings of A, B and C were discussed in previous Office actions as well as supra. A, B and C did not specifically teach the use of THP-01 cells.

Wyllie et al. (US 2003/0235890) teach that RAW cells as well as THP-1 cells were both known for being immunopotentiating models (see [0306] for example).

One of ordinary skill in the art woud have been motivated to substitute THP-1 cells for the RAW cells of Rininger et al. because THP-1 cells would have been a better model for human *in-vivo* immunopotentiating ability of Echinacea products.

Further, Applicant has not indicated, nor is there any data present which would indicate that the use of THP-1 cells would provide for any additional/unexpected benefit over RAW 264.7 cells. Each THP-1 (human) and RAW 264.7 (murine) are both macrophage/monocyte cells which express cytokines such as TGF α and Interleukins and both are known in the art to be used *in-vitro* to assess immunopotentiating activity of analyte compounds. Therefore one of ordinary skill in the art would have a reasonable expectation that either cell would be suitable for quantitating immunopotentiating activity.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

December 8, 2006